

US008648106B2

## (12) United States Patent

### Roychowdhury et al.

## (10) Patent No.:

US 8,648,106 B2

#### (45) **Date of Patent:**

\*Feb. 11, 2014

# (54) **DEXMEDETOMIDINE PREMIX FORMULATION**

(71) Applicant: **Hospira, Inc.**, Lake Forest, IL (US)

(72) Inventors: Privanka Roychowdhury, Foster City,

CA (US); Robert A. Cedergren,

Libertyville, IL (US)

(73) Assignee: **Hospira, Inc.**, Lake Forest, IL (US)

(\*) Notice: Subject to any disclaimer, the term of this

patent is extended or adjusted under 35

U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-

claimer.

(21) Appl. No.: 13/867,861

(22) Filed: Apr. 22, 2013

(65) **Prior Publication Data** 

US 2013/0237576 A1 Sep. 12, 2013

#### Related U.S. Application Data

- (63) Continuation of application No. 13/678,260, filed on Nov. 15, 2012, now Pat. No. 8,436,033, which is a continuation of application No. 13/541,524, filed on Jul. 3, 2012, now Pat. No. 8,338,470, which is a continuation of application No. 13/343,672, filed on Jan. 4, 2012, now Pat. No. 8,242,158.
- (51) Int. Cl.

*A61K 31/164* (2006.01) *C07D 233/56* (2006.01)

(52) U.S. Cl.

USPC ...... **514/396**; 514/816; 548/346.1

(58) Field of Classification Search

None

See application file for complete search history.

#### (56) References Cited

#### U.S. PATENT DOCUMENTS

4,910,214 A	A 3/1990	Karjalainen et al.
5,344,840 A	A 9/1994	Maze et al.
5,716,988 A	A 2/1998	Ibrahim et al.
6,716,867 H	31 4/2004	Aantaa et al.
6,806,291 E	31 10/2004	Sunkel et al.
8,242,158 H	31 8/2012	Roychowdhury et al.
8,338,470 H	31 12/2012	Roychowdhury et al.
8,436,033 E	31 5/2013	Roychowdhury et al.
8,455,527 E	31 6/2013	Roychowdhury et al.
2010/0094219 A	<b>A</b> 1 4/2010	Kriesel et al.
2010/0197694 A	A1 8/2010	Horn
2010/0305160 A	A1 12/2010	Brummett
2010/0326868 A	A1 12/2010	McClain et al.
2011/0152271 A	A1 6/2011	Horn
2011/0230534 A	A1 9/2011	Miyawaki et al.
2011/0269666 A	<b>A</b> 1 11/2011	Quintin

#### FOREIGN PATENT DOCUMENTS

3/2010

#### OTHER PUBLICATIONS

U.S. Appl. No. 13/343,672, filed Jan. 4, 2012.

U.S. Appl. No. 13/541,524, filed Jul. 3, 2012.

U.S. Appl. No. 13/678,148, filed Nov. 15, 2012.

U.S. Appl. No. 13/678,260, filed Nov. 15, 2012.

U.S. Appl. No. 13/343,672, Jul. 18, 2012 Issue Fee payment.

U.S. Appl. No. 13/343,672, Apr. 18, 2012 Notice of Allowance.

U.S. Appl. No. 13/343,672, Mar. 13, 2012 Response to Non-Final Office Action (Accelerated Exam).

 $U.S.\ Appl.\ No.\ 13/343,672, Feb.\ 13, 2012\ Non-Final\ Office\ Action.$ 

U.S. Appl. No. 13/541,524, Nov. 20, 2012 Issue Fee payment.

U.S. Appl. No. 13/541,524, Oct. 22, 2012 Notice of Allowance.

U.S. Appl. No. 13/541,524, Sep. 17, 2012 Response to Non-Final Office Action and Terminal Disclaimer filed.

U.S. Appl. No. 13/541,524, Aug. 17, 2012 Non-Final Office Action.

U.S. Appl. No. 13/678,148, May 9, 2013 Issue Fee payment.

U.S. Appl. No. 13/678,148, Jan. 11, 2013 Notice of Allowance.

U.S. Appl. No. 13/678260, Apr. 8, 2013 Issue Fee payment.

U.S. Appl. No. 13/678,260, Jan. 8, 2013 Notice of Allowance

"Dexmedetomidine HCL Draft Labeling: Precedex™ Dexmedetomidine Hydrochloride Injection," FDA approved label, dated Dec. 17, 1999, and available online Jul. 26, 2001, pp. 1-13. Downloaded from <a href="http://www.accessdata.fda.gov/drugsatfda\_docs/nda/99/21-038">http://www.accessdata.fda.gov/drugsatfda\_docs/nda/99/21-038</a> Precedex\_prntlbl.pdf> on Jan. 4, 2012.

FDA Memorandum from Cynthia G. McCormick, M.D., Director, Division of Anesthetics, Critical Care and Addiction Drug Products, dated Nov. 30, 1999, in connection with the Medical Reviews of the Precedex (dexmedetomidine hydrochloride injection) Application No. 21-038 submitted to the FDA by Abbott Laboratories on Dec. 18, 1998, and available on the FDA website Jul. 26, 2001. Downloaded on Mar. 7, 2012 from <a href="http://www.accessdata.fda.gov/drugsatfda\_docs/nda/99/21-038\_Precedex.dfm">http://www.accessdata.fda.gov/drugsatfda\_docs/nda/99/21-038\_Precedex.dfm</a>.

Petersen, "Trends in Pharmaceutical Primary Packaging for Injectables—Solutions for New Challenges," *Drug Development and Delivery*, Issue Date: Sep. 2012, Posted on: Sep. 5, 2012. Downloaded on Sep. 14, 2012 from < http://www.drug-dev.com/ME2/dirmod.asp?mod=Publications%3A%3AArticle

&mid=8F3A7027421841978F18BE895F87F87F791&tier=4 &id=C2347A2CEAE1422DAA7E592E47648D77 >.

Precedex® Package Insert, Document EN-2680, Hospira, Inc., Sep. 2010, downloaded on Aug. 10, 2012 from <URL:http://www.precedex.com/wp-content/uploads/2010/11/Precedex\_PI.pdf>, pp. 1-24.

(Continued)

Primary Examiner — Savitha Rao Assistant Examiner — Gregg Polansky

(74) Attorney, Agent, or Firm — Baker Botts LLP

#### (57) ABSTRACT

The presently disclosed subject matter relates to pharmaceutical compositions comprising dexmedetomidine or a pharmaceutically acceptable salt thereof wherein the composition is formulated as a liquid for parenteral administration to a subject, and wherein the composition is disposed within a sealed container as a premixture. The pharmaceutical compositions can be used, for example, in perioperative care of a patient or for sedation.